



August 25, 2016

**Consideration of candidates to serve as
ad hoc members of FIFRA SAP (Oct 18-21, 2016)
to review the data relevant to carcinogenicity of glyphosate**

EPA-HQ-OPP-2016-0385

EPA Federal Register announcement 26 July 2016

<https://www.gpo.gov/fdsys/pkg/FR-2016-07-26/html/2016-17707.htm>

Comments submitted to Steven Knott, DFO, Office of Science Coordination and Policy (7201M); telephone number: (202) 564-0103; email address: knott.steven@epa.gov and to the docket at www.regulations.gov EPA-HQ-OPP-2016-0385

The following comments are being submitted on behalf of: the Natural Resources Defense Council, Friends of the Earth US, Maryland Pesticide Education Network, Food and Water Watch, Beyond Pesticides Environment America, and Toxic Free North Carolina. These groups have no direct or indirect financial or fiduciary interest in the manufacture or sale of any chemical that would be the subject of the deliberations of this Committee.

We respectfully remind EPA staff of its professional and legal duty to select panel members who represent the protection of human health and the environment, consistent with the mission of EPA. The Agency cannot accomplish this vital mission if its regulatory priorities and health concerns are dictated by people who have a financial stake in encouraging EPA to do as little as possible to regulate hazardous materials and products.

Glyphosate carcinogenicity

In early 2015 The International Agency for Research on Cancer (IARC) - the cancer evaluation arm of the World Health Organization - convened a meeting of 17 scientific experts from 11 countries to review the cancer data regarding glyphosate. The IARC experts unanimously voted to classify glyphosate as a probable (Group 2A) human carcinogen, based on three lines of evidence:¹

¹ <https://www.nrdc.org/experts/jennifer-sass/glyphosate-herbicide-linked-cancer-iarc-world-health-organization-assessment>

- "sufficient" evidence of cancer in mice and rats that were fed glyphosate over a several years (see reports by EPA 1991 and the WHO 2004);
- "strong" evidence from mechanistic or cellular studies that explain how glyphosate may cause cancer;
- And, "limited" evidence from epidemiologic studies of people, particularly pesticide applicators and farmworkers.

IARC is specifically qualified to conduct such chemical cancer assessments like this one. IARC has been conducting such reviews for forty years, and has evaluated hundreds of chemicals. IARC is considered an authoritative body by governments around the world, and non-industry experts testify as to its integrity and scientific credibility, often in the face of harsh criticism from the industries whose products are being reviewed (Pearce et al 2015).² Nonetheless, Monsanto and its sponsored consultants have relentlessly argued with IARC's assessment since then.

Meanwhile, another wing of the World Health Organization, the European Food Safety Agency (EFSA), reviewed glyphosate later in 2015 and found it unlikely to be carcinogenic or genotoxic, based on a draft assessment provided by Monsanto.³ The dramatic inconsistency between the EFSA and IARC cancer reports spurred 96 prominent scientists from 25 countries to voice strong opposition to the EFSA report. Their letter to the European Commission states that the IARC decision is "by far the more credible," and urges the European Commission to "disregard the flawed EFSA finding on glyphosate" (Portier et al 2016).⁴ In contrast to the industry-dominated job relied upon by EFSA, IARC conducted an independent and extensive review of all the publicly available evidence linking glyphosate to cancer.

Now, it is the US EPA's turn, and a leaked draft indicates that EPA is leaning towards Monsanto's findings of no cancer risk.⁵ This is particularly alarming for a chemical that is used in over 750 herbicide products and applied to fields in the US at over 250 million pounds annually (USGS 2012 data).⁶ The IARC review underscores the need for US EPA to examine and act on all we've learned about glyphosate's dangers in the two decades since it was last approved for use.

Needless to say we are very concerned that Monsanto is putting tremendous pressure on EPA regarding what experts will be selected for the SAP in mid-October. We therefore remind EPA of its obligations to transparency and public trust in convening a SAP that does not include members with financial conflicts or industry bias.

Comments on conflict and disclosure

The scientific credibility of the EPA is damaged by committees with real or perceived bias

The mission of the SAP is to provide credible and independent scientific analysis and advice to government. Panels whose members have conflicts of interest or a strong bias toward the perspective of regulated industries undermine the credibility of the EPA. EPA should make strong efforts to protect its objectivity, integrity, independence, and competence as its most valuable asset. The scientific credibility of the SAP and the EPA is damaged by panels with real or perceived bias.

² <http://ehp.niehs.nih.gov/1409149/>

³ <https://www.nrdc.org/experts/jennifer-sass/glyphosate-iarc-got-it-right-efsa-got-it-monsanto>

⁴ <http://jech.bmj.com/content/early/2016/03/03/jech-2015-207005.full>

⁵ <http://www.reuters.com/article/us-usa-glyphosate-epa-idUSKCN0XU01K>

⁶ http://water.usgs.gov/nawqa/pnsp/usage/maps/compound_listing.php

By law, EPA committees must be composed in order to ensure that industry bias is publicly disclosed, minimized, and eliminated if possible.

The Federal Advisory Committee Act (FACA) imposes requirements on agencies when they establish or utilize any advisory committee, defined as a group of individuals, including at least one non-federal employee, which provides collective advice or recommendations to the agency. 5 U.S.C. App. II, § 3(2). When an agency seeks to obtain such advice or recommendations, it must ensure the advisory committee is "in the public interest," id. App. II, § 9(2), is "fairly balanced in terms of points of view represented and the function to be performed," id. § 5(b)(2), and does not contain members with inappropriate special interests. Id. § 5(b)(3).

Committee membership should exclude financially conflicted members, so that committees are composed of scientists who are able to provide a fair and complete review of all relevant data or issues. If industry representatives have specific knowledge or expertise of value to the deliberations of a committee, then invitations to address the committee during public meetings are appropriate.

Need for transparent and effective disclosure policies

EPA must strictly enforce its own disclosure and conflict policies. Effective disclosure policies play an essential role in protecting EPA and committee work products. If such interests are discovered later, it may seem that either the EPA or the individual was intentionally hiding this information from the public, thereby casting doubt on the SAP work products, and on EPA's ability to identify conflicts and enforce its own policies.

Thank you for the opportunity to provide comments,

A handwritten signature in cursive script that reads "Jennifer Sass".

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